UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

K.C., *et al.*,

Plaintiffs,

v.

THE INDIVIDUAL MEMBERS OF THE MEDICAL LICENSING BOARD OF INDIANA, in their official capacities, *et al.*,

Defendants.

No. 1:23-CV-595

EXPERT REBUTTAL DECLARATION OF DANIEL SHUMER, M.D.

I, Daniel Shumer, M.D., hereby declare and state as follows:

1. I am over 18 years of age, of sound mind, and in all respects competent to testify.

2. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

3. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

4. I incorporate as part of this rebuttal declaration my opinions and qualifications set forth in the expert declaration I filed in this matter dated April 18, 2023 and filed on April 21, 2023. Since that date, I have testified as an expert at trial in: *Dekker et al., v. Weida et al.*, No. 4:22-cv-325 (N.D. Fla.).

5. As with my expert declaration, my opinions contained in this rebuttal declaration are based on, in part, my extensive experience working with and treating children and adolescents with endocrine conditions, my extensive experience working with and treating children and adolescents with gender dysphoria, which I have been treating since 2015, as well as my ongoing

review of the research in these areas of medicine and my conversations with colleagues across the United States. I have personally evaluated and treated over 400 patients with gender dysphoria. C.S. Mott Children's Hospital's Children and Adolescent Gender Services Clinic, which I founded and where I serve as clinical director, has treated over 600 patients since its founding. I actively conduct research related to transgender medicine, gender dysphoria treatment, and mental health concerns specific to transgender youth.

6. I submit this rebuttal declaration to respond to the expert declarations of Drs. James Cantor, Paul Hruz, Kristopher Kaliebe, Dianna Kenny, and Daniel Weiss.

7. In this rebuttal, I respond to some of the central points made in those declarations. I do not address each and every assertion made in those reports that I believe are baseless, misleading, or mischaracterizations of the evidence, as there are many. Instead, my aim is to provide an explanation of the erroneous premises upon which their conclusions are based.

SUMMARY OF OPINIONS

8. The treatment protocols for adolescents with gender dysphoria require rigorous informed consent processes and mental health assessments prior to the prescription of puberty blockers or hormone therapy.

9. "Puberty blockers," i.e. gonadotropin-releasing hormone agonists ("GnRHa") are safe and effective for treating adolescents with gender dysphoria. This treatment is based on robust research and clinical experience, which consistently demonstrate safety and efficacy.

10. Hormonal interventions, e.g. testosterone for transgender boys and young men or estrogen and testosterone suppression for transgender girls and young women, are safe and effective for treating adolescents with gender dysphoria. This treatment is also based on robust research and clinical experience, which also consistently demonstrate safety and efficacy.

11. The State's expert witnesses' evaluation of the Minor Plaintiffs' medical records suggests a lack of familiarity with the patient population of adolescents with gender dysphoria.

TREATMENT PROTOCOLS FOR ADOLESCENTS WITH GENDER DYSPHORIA

12. The State's experts suggest that clinicians routinely provide medical interventions to adolescents without proper mental health assessments and without informing patients and their parents of the potential risks of treatment. I cannot speak to the practice of every clinician in the country, but both the Endocrine Society Clinical Practice Guideline (the "Endocrine Society Guideline") and the World Professional Association of Transgender Health Standards of Care (the "WPATH SOC") require rigorous mental health assessments and informed consent processes before any medical treatment is initiated. (Coleman, et al., 2022; Hembree, et al., 2017).

13. In my experience personally treating over 400 youth with gender dysphoria, and as the clinical director for the Child and Adolescent Gender Services Clinic, each patient undergoes an extensive psychological assessment and, if medical interventions are deemed medically appropriate, an extensive informed consent process before such interventions is provided.

14. In my practice, I regularly communicate with practitioners who treat adolescents with gender dysphoria. The assessment and informed consent process that we utilize at the Child and Adolescent Gender Services is comparable to the processes used at similar clinics across the country as I understand them. If providers are foregoing assessments and informed consent, such practice would be outside the recommended guidelines for care.

15. It is not the case that clinicians "encourage" any patient to initiate gender-affirming care as some of the State's experts suggest. (*See* Hruz, ¶ 56). Consistent with the WPATH SOC and the Endocrine Society Guideline, each patient is met first by providers who explore the patient's medical and mental health history and identity. Under the standards of care, no patient

is rushed into medical treatment, and no treatment is initiated without appropriate evaluation and an informed consent process. Consistent with SOC 8, gender clinics use a multidisciplinary approach and the decision to initiate gender affirming care is made by involving relevant disciplines, including mental health and medical professionals, to reach a decision with families about whether medical intervention is appropriate and remain indicated through the course of treatment. (Coleman, et al., 2022; Hembree, et al., 2017). As clinicians our jobs are not to "encourage" any particular identity or outcome but rather to assess and treat our patients.

16. It appears to be the position of the State's experts that "watchful waiting" or delay until a patient turns 18 years of age before initiating medical treatment for gender dysphoria would not cause harm to minor patients. (*See, e.g.*, Kaliebe, ¶ 89). This is inconsistent with a robust body of research and my clinical experience. Many physiological changes that happen during endogenous puberty cause severe distress for patients with gender dysphoria and can be difficult, if not impossible, to reverse with subsequent treatment. Based on my clinical experience, patients with severe dysphoria who are able to receive treatment prior to age 18 experience substantial mental health improvements from gender-affirming medical interventions.

17. The State's experts attempt to discredit WPATH as an advocacy organization. This critique is also misplaced. (*See* Kaliebe, ¶ 126). Like many medical associations, WPATH both advocates for patients and pursues rigorous scientific research. This is not a new phenomenon in medicine. The American Diabetes Association, for example, is a professional association that both advocates for patients with diabetes and is a scientific organization. Similarly, the American Heart Association has scientific meetings, community engagement and advocacy arms.

SAFETY AND EFFICACY OF GnRHa TO TEMPORARILY SUPPRESS PUBERTY

18. GnRHa have been used extensively in pediatrics for several decades. Prior to their use for gender dysphoria, they were used (and still are used) to treat precocious puberty. Extensive data supports their safety and efficacy. It is therefore not accurate to suggest that little is known about the effects of puberty blockers.

19. Though the State's experts warn about delaying puberty, (*see* Cantor, ¶¶ 213, 230; Hruz, ¶¶ 45, 61), use of GnRHa in transgender youth does not delay puberty beyond the typical age range. There is diversity in the age of pubertal onset and duration. Most adolescents begin puberty between ages 10 and 12 years, but puberty may begin as early as 8 or 9 years, or as late as 13 or 14 years (or later in the case of delayed puberty). Protocols used to treat adolescents with gender dysphoria would tend to put them toward the latter end, but still within this typical range. Partly in recognition of the natural diversity in pubertal onset, WPATH SOC 8 removed strict age guidelines for hormone therapy was so that patients moving from GnRHa to testosterone or estrogen could have an individualized assessment about when initiating puberty is appropriate. There is no data to support the State's experts' assumption of that delaying puberty within these normal age ranges will have negative short- or long-term social and developmental consequences.

20. In my clinical experience, GnRHa greatly reduce distress both at the time of treatment and later in life. At the time of treatment, GnRHa reduces the worsening gender dysphoria and mental health deterioration that accompanies the development of secondary sex characteristics incongruent with an adolescent's gender identity. Later in life, patients treated with GnRHa benefit from a reduced need for surgical or other invasive interventions to overcome the effects of endogenous puberty. In my clinical experience, providing individualized care based on individual patient characteristics, using the WPATH Standards of Care as the foundation, provides significant benefit to patients, minimizes gender dysphoria, and can eliminate the need

for surgical treatments in adulthood. The side effects of GnRHa are easily managed, and, for the majority of patients, the risks outweigh the benefits. In my practice, adolescent patients struggling with significant distress at the onset of puberty routinely have dramatic improvements in mood, school performance, and quality of life with the appropriate use of GnRHa. Allowing puberty to progress in such situations often results in worsening distress. This has been what I have observed personally in situations when a patient eligible to receive GnRHa is unable to obtain it for various reasons (lack of insurance, parental disagreement, etc.). Sometimes mood remains relatively stable on GnRHa without marked improvement or deterioration. This is not a sign of treatment failure, but rather a much preferrable outcome to the counterfactual of withholding treatment resulting in mental health deterioration.

21. The State's experts claim that patients treated with GnRHa will experience a range of health consequences. (*See* Cantor, ¶¶ 200-236). For example, they say that patients treated with GnRHa will be at an elevated risk of lower bone mineral density. (*See* Hruz, ¶ 66; Weiss, ¶¶ 92-101). The risk of lower bone mineral density in prolonged use of GnRHa can be mitigated by screening for and (when present) treating vitamin D deficiency, and by limiting the number of years of treatment based on a patient's clinical course. (Rosenthal, 2014). As I explain to my patients, every year, a child's bone density gets a little stronger. When a patient is on GnRHa, their bone density increases every year, at a pre-pubertal speed. During puberty, whether from testosterone or estrogen, bone density increases at a faster rate—a bone density spurt, almost like a growth spurt. Once a patient stops using GnRHa and begins puberty, either endogenously or through exogenous testosterone or estrogen, they will undergo their bone density spurt.

22. The State's experts raise the issue of risk of fracture later in life, (*see* Cantor, ¶ 217; Weiss, ¶ 92), but no such long-term effects have been observed in patients treated with GnRHa

for either precocious puberty or gender dysphoria. As with all of the risks of GnRHa, the risks related to bone mineralization and the state of the evidence are discussed with patients and their parents during the informed consent process and are weighed against the risks of not providing treatment.

23. With respect to claims about weight gain, (*see* Cantor, ¶ 219; Weiss, ¶ 90), it is appropriate to counsel patients on the potential risk of weight gain while using GnRHa, along with the benefits of maintaining a healthy diet and promoting physical activity, and to provide nutritional support for those at risk of obesity. In my clinical experience, families and adolescents consider this potential side effect—common to other medications used to treat endocrine disorders and other conditions in adolescents—when weighing the risks and benefits of treatment. It is also true that patients with untreated anxiety or depression are at higher risk for weight gain, and withholding GnRHa could serve as a risk factor for unhealthy weight.

24. Additionally, the State's experts suggest that patients on puberty blockers will have slower rates of growth in height. (*See* Hruz, ¶ 213). Just as the bone density spurt associated with puberty will not occur while using GnRHa, so too will the growth spurt associated with puberty not occur while using GnRHa. Again, once puberty resumes, either endogenously or through exogenous hormone therapy, adolescents will begin to grow into their adult height. For transgender girls, use of GnRHa may reduce final adult height somewhat, but that is usually considered a benefit of treatment and consistent with gender-affirming goals. For transgender boys, treatment increases final adult height which is very often consistent with gender-affirming goals as well.

25. The State's experts' claim that brain development occurring during puberty may be negatively affected by GnRHa is not accurate. (*See* Cantor, ¶ 89; Hruz ¶¶ 64-65; Weiss, ¶ 102).

Patients with gender dysphoria who are treated with GnRHa will later undergo hormonal puberty with all the same brain and other developments. I am unaware of any research suggesting that treatment has negative impact on brain development or executive functioning, and I have not seen this in my clinical practice. Such a claim would also be inconsistent with my clinical experience treating patients with delayed puberty. Those individuals still have normal brain development with respect to cognition and executive function despite starting puberty at a similar age as patients with gender dysphoria treated with GnRHa.

SAFETY AND EFFICACY OF HORMONE THERAPY

26. Hormone therapy is safe and effective to treat adolescents with gender dysphoria. As with the use of GnRHa, where medically indicated, testosterone or estrogen (along with a testosterone suppressant) are provided after a discussion among the patient, their parents, and the patient's care team, as well as an extensive informed consent process. Hormone therapy treats gender dysphoria in adolescents by facilitating the development of physical changes congruent with a patient's gender identity.

27. Defendants' claim that hormone therapy is harmful because adolescents receive inappropriately high levels of hormones. (*See* Hruz, ¶ 48; Weiss, ¶¶ 107-108). The goal of hormone therapy is to maintain the patient's hormone levels within the normal range for their gender identity. This is true for all of my patients for whom I prescribe testosterone or estrogen, including non-transgender adolescents with conditions such as delayed puberty, hypogonadism, Turner Syndrome, Klinefelter Syndrome, agonism, premature ovarian failure, and disorders of sex development. Laboratory testing is recommended to ensure proper dosing and hormonal levels within the normal male or female range for the patient's age. We closely track dosing and

circulating hormone levels to minimize any risk of adverse effects, in patients with gender dysphoria and any other conditions requiring hormonal treatment.

28. Treatment of gender dysphoria with testosterone or estrogen is highly beneficial for both short-term and long-term psychological functioning of adolescents with gender dysphoria. (*See* Achille, et al., 2020; Allen, et al., 2019; Chen, et al., 2023; de Lara, et al., 2020; de Vries, et al., 2014; Grannis, et al., 2021; Green, et al., 2022; Kaltiala, et al., 2020; Kuper, et al., 2020). I observe this in my clinical practice: my patients who receive medically appropriate hormone therapy and who are treated consistent with their gender identity in all aspects of life experience significant improvement in their health.

29. The State's experts claim that the risks of hormone therapy include disfiguring acne, high blood pressure, weight gain, abnormal glucose tolerance, breast cancer, liver disease, thrombosis, and cardiovascular disease. (*See* Hruz, ¶¶ 52, 54; Weiss, ¶¶ 105-125). In my clinical experience, transgender boys on testosterone experience acne similar to any other boy going through a testosterone-driven puberty. Breast cancer is more common in people with breasts, but not more common in transgender women when compared to other women. Other medical problems occur no more frequently than what is expected in the general population when hormone levels are monitored and adjusted effectively.

30. The State's experts seem to suggest that hormone treatment is harmful because it leads to a "lifetime" of continuing to receive such therapy. (*See* Cantor, ¶ 223 ("lifetime dependence on cross-sex hormones")). In every encounter with my care team, there is a re-evaluation of treatment, including the benefits, side effects, and trajectory of the treatment for the individual patient. For some patients, they may undergo hormone treatment for a period of time and then discontinue the treatment if dysphoria is well-managed and the changes from the

hormone therapy have adequately addressed the underlying dysphoria. For my patients who do remain on maintenance doses of hormone therapy, the risks of ongoing hormone therapy can be well-managed and are not unlike risks associated with those present for other patients who undergo long-term sex hormone therapy for different conditions like Kleinfelter's Syndrome, Turner Syndrome, patients who have to have their ovaries or testicles removed due to cancer, torsion or other causes as well as those with hypopituitarism. Many endocrine conditions are lifelong and require lifelong use of hormone replacement including Type 1 diabetes and hypothyroidism, which require insulin or thyroid hormone treatment for life, respectively. Ultimately, many endocrine conditions are treated with lifelong medical management – including hormone therapy – and that does not pose an inherent risk to patient health but rather is critical to patient health.

31. Defendants' experts also discuss the fertility implications of gender-affirming care. (*See* Cantor, ¶¶ 89, 204-205; Hruz, ¶¶ 51-52, 89; Weiss, ¶¶ 96-98, 110). The sweeping suggestion that hormone therapy affects fertility for all patients is simply incorrect. As set forth below, there are options for preserving the fertility of adolescents with gender dysphoria who first begin treatment with GnRHa and then proceed to hormone therapy, and adolescents who undergo their endogenous puberty prior to commencing hormone therapy often achieve fertility upon cessation of exogenous hormone therapy.

32. For minors who are first treated with GnRHa, there is decades of research showing that GnRHa alone has no long-terms implications for fertility. (Guaraldi, et al., 2016; Martinerie, et al., 2021). Progression through natal puberty is required for maturation of egg or sperm. If a patient who first received GnRHa and then hormone therapy wishes to be fertile, they can withdraw from exogenous hormones and allow pubertal progression. Caanen et al. demonstrated

that transgender men have similar ovarian morphology to cisgender women, even when treated with GnRHa followed by testosterone. These treatments did not cause the ovarian changes which are seen in hyperandrogenic women with polycystic ovarian syndrome and infertility. (Caanen, 2017). This lends support to the expectation that the sequence of GnRHa to testosterone does not necessarily cause permanent infertility.

33. Patients who initiate hormones after completing puberty are offered gamete preservation prior to hormonal initiation. (Coleman, et al., 2022). But even when patients do not undertake gamete preservation, withdrawal of hormones in adulthood often is successful in achieving fertility when it is desired. (Light, et al., 2014; Knudson, et al., 2017). For transgender men and women, pregnancies have occurred even when on testosterone or estrogen treatment, and transgender patients are regularly advised that testosterone and estrogen are not effective forms of birth control.

34. For all medications with potential impacts on fertility, the potential risks and benefits of both treatment and non-treatment should be reviewed and data regarding risk for infertility clearly articulated prior to the consent or assent of the patient. Risk for fertility changes must be balanced with the risk of withholding treatment. All of these risks—which the State's experts, in my opinion, overstate—are disclosed to parents and youth during the informed consent process, during which families can weigh the risks and benefits before making a decision. This decision-making process is not unique to the treatment of gender dysphoria in the pediatric patient populations. Medications used for other conditions, such as chemotherapy, can affect fertility, and the risks for fertility changes must be balanced against the risk of withholding treatment.

35. The State's expert witnesses also critique an update to the WPATH SOC, which no longer sets more rigid age limitations around the initiation of hormone therapy. (*See* Hruz, ¶ 59).

This allows for flexibility in caring for patients who have a need to access hormones earlier due to early puberty or earlier onset and severity of dysphoria. This is consistent with the practice of individualized medicine, using WPATH SOC as a foundation.

36. Ultimately, in my clinical experience, gender-affirming medical care dramatically improves the health and well-being of adolescents with gender dysphoria for whom the care is medically indicated.

37. For patients for whom these medical interventions are indicated, withdrawing GnRHa or hormone therapy is harmful. Discontinuation of GnRHa would cause the onset of a puberty discordant from gender identity, a significant source of distress for patients with gender dysphoria. Similarly, discontinuation of gender-affirming hormone therapy for adolescents with gender dysphoria will cause adolescents receiving treatment to experience physiological changes inconsistent with their gender identity. An increase in gender dysphoria can increase depression, anxiety, self-harm, hospitalizations, and suicidality in transgender adolescents. These permanent changes can lead to the need for future surgical interventions that could have been prevented by maintaining earlier treatment.

38. As the clinical director of the Children and Adolescent Gender Services Clinic, I see patients who typically live in Michigan or Ohio. Even with our clinic and clinics like ours, families often have difficulty in accessing gender-affirming care, including long wait times and barriers associated with insurance and travel. Prior to this current legislation's passage, providers from Indiana contacted me for information about gender affirming care in Michigan anticipating that many families would come north for this care. I anticipate this will occur if this legislation succeeds, access to care will become even more challenging, and it will become restricted to Hoosier families financially able to travel out of state. The longer the patient is unable to access

their medically necessary care, the worse their suffering will be. In addition, transgender youth are often wary of medical providers and can take longer to develop a therapeutic and trusting relationship with their provider. This change in providers can set them back in their care and can have lasting physical and mental health effects.

THE STATE'S EXPERTS' REVIEW OF THE MINOR PLAINTIFFS' MEDICAL RECORDS

39. I have reviewed the comments made by Drs. Kenny and Weiss regarding the Minor Plaintiffs' medical records. (*See* Kenny, ¶¶ 187-246; Weiss, ¶¶ 28-35). Without addressing each and every issue, there are at least three significant thematic errors in their assessments.

40. First, Drs. Kenny and Weiss assume that the existence of other medical conditions precludes treating gender dysphoria, or that treatment of gender dysphoria occurred to the exclusion of treating other comorbidities. (*See* Kenny, ¶¶ 240-246; Weiss, ¶ 28). That is inconsistent with the WPATH Standards of Care and the Endocrine Society Guideline, both of which recommend comprehensive mental health assessments for adolescents with gender dysphoria prior to initiating treatment. In my clinical practice, as part of our individualized treatment of every patient, we consider whether or to what extent a patient's other medical conditions, and their management, may affect the suitability of gender-affirming treatments like GnRHa or hormone therapy. A categorical skepticism of using GnRHa or hormone therapy to treat gender dysphoria based on the existence or other comorbid conditions suggests a lack of familiarity with this patient population.

41. Second, Drs. Kenny and Weiss assume that the age of the onset of gender dysphoria calls into question the accuracy or legitimacy of the underlying diagnosis. (*See* Kenny, ¶ 235; Weiss, ¶ 30). I have treated patients whose gender dysphoria became apparent and clinically

significant pre-pubertally, and I have also treated patients for whom the onset of puberty created clinically significant distress and the appearance of expressed symptoms of gender dysphoria for the first time. Given the comprehensive assessments required by WPATH Standards of Care and the specificity of the diagnostic criteria in the DSM-5 TR, I do not consider the age of onset alone to be a reason to question the accuracy of the diagnosis, although in my clinical practice we do take into account the persistence of the feeling of incongruence when evaluating the appropriate course of treatment. It is also my experience, in speaking with my patients, that many of them experience gender dysphoria for quite some time before informing their parents, or anyone, and so the age at which they confide in an adult about their feelings or present for treatment does not always reflect the age at which they began experiencing distress.

42. Third, Drs. Kenny and Weiss assume that transgender identity or experience of gender dysphoria arises from trauma. (*See* Kenny, ¶¶ 196, 204-206; Weiss, ¶¶ 29, 32, 33). In my clinical practice, I have treated patients who have experienced various kinds of trauma, and those who have not. The multidisciplinary team that I practice within considers the full patient history when evaluating an adolescent for gender dysphoria, and we consider the whole patient when discussing with parents and the patient themselves the appropriate course of treatment for their condition.

43. In my clinical experience, providing individualized care based on individual patient characteristics, using the WPATH Standards of Care as the foundation, provides significant benefit to patients, minimizes gender dysphoria, and improves patient outcomes. In the Children and Adolescent Gender Services Clinic, we encounter patients with other medical conditions. As part of our holistic treatment of the entire patient, we carefully consider what other support our patients with gender dysphoria need in addition to treatments directly addressing their gender dysphoria.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 7th day of June, 2023.

Daniel Shumer, M.D.

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